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Washington, D.C. 20505

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MEMORANDUM FOR: Dr. Gordon Wallace
Executive Office of the President
Office of Science and Technology Policy

FROM : [REDACTED] 25X1
Director of Scientific and Weapons Research

SUBJECT : Agricultural Biotechnology [REDACTED]

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The attached memorandum is in response to your request for an up-to-date assessment of Agricultural Biotechnology. We hope this information will be useful to you and your staff. [REDACTED]

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Attachment:
SW M 84-10030



SW M 84-10030



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SUBJECT: Agricultural Biotechnology [redacted]

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OSWR/STD/LSB [redacted]

(11 April 84)

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Central Intelligence Agency

Washington D.C. 20507

DIRECTORATE OF INTELLIGENCE

11 April 1984

Agricultural Biotechnology [redacted]

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Summary

West European and Japanese programs for supporting biotechnology have wide variations in the extent of government funding, direction, and control. All of these programs are concerned with developing manpower, handling information, and commercializing basic research. They are directed toward and for the most part should achieve increased commercial competitiveness with other biotechnologically advanced countries.

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This memorandum was prepared by [redacted] Office of Scientific and Weapons Research. Comments or questions may be directed to the Chief, Life Sciences Branch, Science and Technology Division, OSWR, [redacted]

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AGRICULTURAL BIOTECHNOLOGY

Agricultural biotechnology uses cellular and sub-cellular biological processes for the large scale production of agricultural goods and services. It is an applied technology rather than a research science, since applications to industrial processes occurred many years prior to the discovery of their scientific basis. The development of newer tools (genetic engineering and recombinant DNA methods) has enhanced the potential to rapidly, specifically and efficiently increase productivity and improve agricultural varieties.

Table 1 provides an overview of anticipated industrial applications of biotechnology, including food and agriculture applications. [redacted]

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Table 1: BIOTECHNOLOGY: BY INDUSTRIAL SECTOR [redacted]

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SECTOR	ACTIVITY/Products
Chemicals: organic	ethanol, acetone, butanol, organic acids
	enzymes, polymers
inorganic	bioaccumulation and leaching (Copper, Uranium)
Pharmaceuticals	antibiotics, diagnostic agents, vaccines
Energy	ethanol, methane, biomass
Food	novel foods, baker's yeast, amino acids, vitamins, glucose and high fructose syrups, food additives, beverages
Agriculture	animal feedstuffs, veterinary diagnostics and vaccines, microbial pesticides, nitrogen-fixing bacterial inoculants, plant cell and tissue culture (vegetative propagation, embryo production, genetic improvement)
Service industries	water purification, waste management, oil recovery, effluent treatment, analytical tools

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Biotechnology offers opportunities to increase the efficiencies and productivities of crops and animals by modifying their genetic characteristics. Since species barriers to cross-breeding genetic characteristics can be circumvented by the use of the newer biotechnologies, a greatly expanded number and quality of genetic modifications have now become conceivable.

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Benefits from the application of these technologies include:

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IN PLANTS

- o increased yields
- o hardier plants, extending growing seasons and geographical range
- o reducing growth cycles to permit more harvests per season
- o increasing density per acre
- o strengthening resistance to pests, diseases, heat, frost, drought
- o increasing the ratio of edible material to waste

IN ANIMALS

- o enhanced disease resistance
- o improved environmental resistance
- o increased growth
- o better feed conversion
- o more of desirable consumer products and characteristics.

National and private interests are competing for market shares in a world market that for veterinary pharmaceuticals and vaccines now exceeds \$10 billion and that in plant biotechnology could reach \$20 billion or more for the 10 major crops by the year 2010.

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Agriculture was among the first beneficiaries of biotechnology. Improved livestock vaccines and growth stimulants or hormones have been developed and marketed. Improved disease diagnostic reagents for plants and animals are only a few years away, and improved plant and animal varieties are expected within a decade. The impact of biotechnology on agriculture and the food industry will be greater than for other industries. Improved agricultural

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vaccines and pharmaceutical products will be commercially available sooner than human medical products primarily due to the less rigid, lengthy, and expensive regulatory requirements necessary for agricultural drugs and biologics. Herbicide resistant plants and other environmental stress resistant plants that are the product of current extensive investments by the chemical industry will take longer to reach market levels.

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TECHNOLOGY DEVELOPMENT

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The overall development of biotechnology depends on multiple lines of research applying the same basic techniques to a wide range of end items. These developments will follow a general trend:

- o initial discoveries and exploitation of single-celled life forms such as bacteria, yeast, fungi
- o application of knowledge for manipulating higher, multi-celled plants and animals, and
- o reverse engineering, such as insertion of traditional animal protein nutrients into plant varieties, to manufacture products more economically and efficiently.

Currently, biotechnology is in the first development stage of application in bacteria and yeast and has just begun to be applied to basic studies of higher plants and animals.

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World-wide, over 1000 companies, institutes, or universities in at least 27 countries are involved in basic, applied, or engineering development in biotechnology. Commercial development is currently faced with a number of drawbacks and rate-limiting factors:

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- o more basic research is needed to establish an information foundation on which applied R&D can be based
- o practical experience at the applied level is needed
- o information on process engineering is still scanty
- o patents will be hard to enforce
- o competition will be fierce, and hence expensive and risky
- o products and processes may become obsolete quickly.

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NATIONAL DEVELOPMENT PROGRAMS

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National governments have started programs to enhance industrial progress and competitiveness in biotechnology by increasing the:

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- o Quantity and quality of trained manpower
- o Free flow of information and rapid access to current technical information to support the transition of basic research to industrial processes
- o Monetary and industrial bases supporting basic research and commercial exploitation

Trained manpower availability is a major factor because the skills required by biotechnology cover a wide spectrum including:

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- o natural sciences
- o chemical engineering
- o control engineering
- o electronic engineering
- o process engineering
- o integrated management of research and development

Free flow and rapid access to current information is an essential element of the movement from basic research to commercialization and the subsequent feedback of information from industry to the research base.

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Financial and industrial bases to support applications research are most important during the commercial development phase of a product.

Commercialization can require from 5 to 10 years after basic laboratory development and is the most financially intensive as well as the most risky phase of development.

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Two models of biotechnology support and development illustrate the extremes in approach:

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Government Directed

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Government: Centrally planned development
 Oversight committees for education and industry
 Government funding of basic and applied research

Industry: Integrates commercialization programs with government direction.
 Depends on government targeting for areas of development.

Industry Directed

Government: Provides favorable regulatory and economic climate
 Supports training of indigenous personnel, education
 Offers conditions such that corporations
 attract scientists, utilize local
 labor, and develop their own lines of profitable research

Industry: Determines own research and business area
 Provides R&D funds from own resources

Most governments have developed a mixed approach, with Japan having the most nearly government-directed approach and the Swiss the most industrially-directed. In general, government influence is determined by the economic strength of the nation, culture of the country, prevalence of multinational companies, and traditional methods of government action. The development of national programs has tended to be more evolutionary than revolutionary.

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The European Economic Community (EEC) and its member states have the most complex program. It consists of the organization's program and individual programs of its member states. Table 2 shows 1983 estimates of European, US, and Japanese Government spending.

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Table 2: BIOTECH FUNDING 1983 (est.)

(\$ millions)

	BioTech R&D	BioTech Relevant R&D
West Germany	30	109
France	26	70
UK	38	49
Italy	10	29
Netherlands	9	22
Belgium	7	12
Total =	(120)	(291)
USA	196	522
Japan	51	?

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MAJOR EUROPEAN PROGRAMS

The following are short summaries of the major European programs:

EEC

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- Objectives**
- o Unified approach to training, research
 - o Standardization of regulations
 - o Market regulation
 - o Harmonization of national markets

- Government Authority**
- o Director General for Science, Research, and Development

- Program History**
- o Program proposed-1977
 - o Program accepted-1981
 - o Start -1982
 - o Phase I- 50 projects in leading bioscience laboratories focus on agriculture and food industry by genetic engineering and second generation bioreactors
 - o Phase II- 1983-increase support to 100 projects and move part of focus to fine chemicals and pharmaceuticals

- Industry Participation**
- o Minor involvement

- Strengths**
- o Basic science network could be important in linking various national groups in
 - + animal vaccines
 - + dairy industry
 - + plant genetics
 - + nitrogen fixation

- Weakness**
- o Politically inspired solution, national self-interest is divisive
 - o Basic problems
 - + Lack of qualified scientists and engineers
 - + Inadequate industry/university co-operation

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- + Insufficient and late funding by private industry
- + Migration of scientific talent from Europe (brain drain)
- + National and Regional plans will result in political conflicts.

UNITED KINGDOM

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|------------------------|---|
| Objectives | <ul style="list-style-type: none"> o Provide adequate trained manpower o Retention of public and private scientific talent o Balanced development by government support of areas that are neglected by industry |
| Government Authority | <ul style="list-style-type: none"> o Agricultural and Food Research Council (AFRC) |
| Program History | <ul style="list-style-type: none"> o Early fragmented private and government studies-1977-1980 o Five Year Corporate Plan (AFRC) details "substantial and continuing" reductions in its budget |
| Industry Participation | <ul style="list-style-type: none"> o Important involvement--Welcome, Unilever (UK), and Searle (UK) are world leaders in veterinary vaccines and pharmaceuticals |
| Strengths | <ul style="list-style-type: none"> o Strong industry participation in veterinary associated biotechnology o Second to US in participation of small venture capital companies with academic participation o Superior training institutions |
| Weaknesses | <ul style="list-style-type: none"> o British Government, unwilling or unable to commit additional resources o Large public unrest and visibility due to support of common market agricultural plan and attendant surplus commodities. o Migration of scientific talent to US |

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FRANCE

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- Objectives**
- o Increase trained manpower
 - o Facilitate transfer of information from research to industry
 - o Retain French market share in seeds and vaccines
 - o Support traditional French strengths-dairy, animal vaccines, plant breeding
- Government Authority**
- o Policy-Guidance Committee for Strategic Industry (CODIS)
 - o Operations-Ministry of Research and Industry
- Program History**
- o The French government considers biotechnology as a critical national resource and has closely guarded or classified their major programs. Interest started in 1977 or 1978 and the first major elements (i.e. control of patents and publications) began to appear in 1982-83.
- Industry participation**
- o Private industry puts only 0.1% to 0.2% of its income into research
 - o French government wants industry to put 2.5% of income into research
- Strengths**
- o Traditional and well developed infrastructure in vegetable and ornamental seeds and vaccines
- Weaknesses**
- o Primary barrier is lack of venture capital
 - o Additional barriers:
 - + Poor level of coordination between universities and industry
 - + Anti-industry attitude of researchers
 - + Lack of mobility of scientific workers
 - + General lack of trained research personnel
 - o Secrecy inhibits information transfer within the country

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FEDERAL REPUBLIC OF GERMANY

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|------------------------|---|
| Objectives | <ul style="list-style-type: none"> o Increased budgetary priority o Promotion of basic studies o Organizational development |
| Government Authority | <ul style="list-style-type: none"> o Federal Ministry for Research and Technology (BMFT) |
| Program History | <ul style="list-style-type: none"> o Developed late, initial interest in 1980 with reorganization and development still active o Program puts emphasis on a few major institutions |
| Industry participation | <ul style="list-style-type: none"> o Private industry spending \$90 million o Private money is basically from a few chemical giants--BASF, Hoechst, Bayer, and Schering o Small venture capital firms almost non-existent |
| Strengths | <ul style="list-style-type: none"> o Concentration of research in veterinary diagnostics and pharmaceuticals and development of plants with herbicide resistance o Large portion of research is carried out in foreign countries based on joint research ventures and other proprietary agreements. |
| Weaknesses | <ul style="list-style-type: none"> o Narrow focus o Shortage of highly qualified scientists o Emigration of trained scientists o Lack of industrial support in bioreactors and bioengineering |

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OTHER EUROPEAN COUNTRIES [redacted]

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Most of the other European countries have biotechnology goals and policies; however, little agricultural development is expected except in a few specific industries. Those industrial efforts worth noting reside in Denmark, Switzerland, and the Netherlands. Denmark has an austere governmental program that has some support of large firms in plant breeding and cheese technology. This program is progressing, but we expect that it will produce only limited results. [redacted]

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Switzerland's biotechnology effort in agriculture is guided by the large pharmaceutical and chemical industries of that country. It is most proficient in producing animal pharmaceuticals and vaccines, and has invested in producing herbicide-resistant plants. [redacted]

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The Netherlands has become proficient in animal biologicals and is currently market-researching a number of animal growth regulators. Their research program is concentrated in a limited number of government and private organizations. [redacted]

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JAPAN

Japan is the major non-European foreign nation involved in biotechnology.

It is consistently cited as a world leader in the field. Its major program can be summarized as:

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Objectives

- o Maintain leadership
- o Enhance training of scientists
- o Acquire state-of-the-art technology by scientific exchanges, joint ventures, and marketing ventures with foreign countries.

Government Authority

- o Ministry of Agriculture, Forestry, and Fisheries (MAFF) with close co-ordination of the Ministry of International Trade and Industry (MITI)

Industry Participation

- o Large Japanese industries have a long history of close governmental co-operation.
- o Greatest integration of government and private industrial programs.

Strengths

- o Highly centralized governmental/industrial program focus on:
 - + Bioreactor system development
 - + Simple diagnostic tests for animal disease
 - + Seed improvement by cell culture
 - + Cell fusion for microorganism and plant cell improvement with the chemical industry targeted on growth regulators, herbicides, and product improvement

- o Developed skills in commercial development of microbial products
- o Extensive penetration of potential competitors by joint ventures and licensing agreements

Weaknesses

- o Perceived leadership position invites foreign interest and attack

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- o Cultural barriers hinder information exchange with foreign scientists
- o Weak foreign marketing structure in agriculture

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IMPLICATIONS OF AGRICULTURAL BIOTECHNOLOGY

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No consensus has been reached among national and international authorities on the true implications of agricultural biotechnology. Based on current trends, we expect the following to impact:

WORLDWIDE AGRICULTURAL BIOTECHNOLOGY MARKETS

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- o Switzerland and Japan will dominate the non-US veterinary pharmaceutical market, with some secondary production centers for low profit materials in Italy.
- o Veterinary biologicals research (vaccines and diagnostics) will be dominated by the United Kingdom and France with some specialized development in the Netherlands.
- o France and the UK will dominate the African veterinary biological market and will use licenses or joint ventures with Japan to dominate the Asian market. US dominance in the South American market will continue.
- o Non-US plant technology will be dominated in the short term by the countries with major chemical industries: such as, Japan, Switzerland, United Kingdom, and Federal Republic of Germany.
- o Short term plant biotechnology will be involved in the development of growth modifiers and herbicide resistant plants.
- o Japan will move in the longer term to plant cell culture with primary emphasis on industrial production of large volume, low cost biomass and bioproducts in large reactors.
- o Field crop modifications will follow traditional interests and strengths: UK, France, Netherlands in ornamentals and vegetables; Japan in rice; and Canada and possibly the Soviet Union in wheat and grains.

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WORLD TRADE

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- o 20% of the gross domestic product of the developed nations is biologically based currently and will be subject to biotechnical change
- o The relative cost significance of products and of products and processes will continuously change due to new technology.
- o Product demand and trade patterns will change in favor of biotechnically derived products because of price.

LESSER DEVELOPED COUNTRIES

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- o Lack the critical mass of scientific talent and industry will prevent them from conducting biotechnology research
- o Most benefits will derive from improved animal vaccines and plant varieties
- o Agriculture lacks the infrastructure to exploit biotechnology effectively
- o Countries depending on biologically derived exports will be forced to compete with biotechnically derived products.

UNITED STATES

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| International trade | <ul style="list-style-type: none"> o Food exports to Soviet Union and other traditional partners could be affected by increased food production based on new plant varieties; however, biotechnology provides opportunity to enhance value of commodities and reduce dependence on foreign sources or create new markets o Increased demands for trade barriers between biotechnically advanced countries to protect their industry. |
| Scientific talent | <ul style="list-style-type: none"> o Competition for scientific and engineering talent between governments and between large multinational corporations will increase. o National programs to reverse the drain of scientific talent, already under consideration by Japan, France, UK, and FRG may result in the loss of scientific talent. Individual scientists will be increasingly |

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targeted for recruitment by foreign private and government entities.

- Information Transfer
- o Both Japan and France are increasing the secrecy and governmental control of biotechnology. The trade-secrets policies of industry are being rapidly expanded to university and governmental institutions.
 - o Joint ventures, licensing agreements, and equity buyouts are increasingly being used by foreign institutions to acquire technology rapidly and inexpensively.
 - o Patent agreements and rights will be subject to dispute and litigation.

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